

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of kappa-2 carrageenan containing compositions in the reply filed on November 15, 2007 is acknowledged.

A species election was also required and although the Applicant did not expressly make an election with traverse, arguments were presented contesting the requirement. Therefore the species election (soft capsule with plasticizer, at least 0.5% by weight of gel kappa-2 carrageenan, at least 50% solids, nutritional/vitamin ingredient as encapsulated material, and no flavorant) has been treated as an election with traverse. It is requested the Applicant clarify the traversal status of this election in the response to this action. The traversal is on the grounds that no undue search burden was presented in the elected invention. This is not found persuasive because the claims were drawn to a film that has a much broader applicability and utility beyond the capsule and solid form claimed. As such, the volume of prior art that would require consideration would be much larger, and therefore burdensome, were it required that all the species

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-33 and 38-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has claimed priority to

provisional applications 60/462785, 60/462617, 60/4626783, 60/462794, 60/462792, 60/462793, 60/462758, and 60/462721.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilleland et al. (U.S. Patent No. 6,375,981) in view of Vries (Interaction of carrageenan with other ingredients in dairy dessert gels. In Gums and Stabilisers for the Food Industry 11 ed. Williams and Phillips).

Gilleland et al. teach a soft capsules made from a soft gel that contain modified starch, hydrocolloid gum and plasticizer, where the film of their invention comprises the capsule wall (see abstract and column 2 lines 24-30; instant claims 34). More specifically, Gilleland et al.

teach that the gel composition is prepared with water and has a solids content of about 30%-70% by weight (see column 1 lines 60-61, claims 1, 3, and 15 ; instant claims 34 and 36). These solids include 25%-75% starch material (second film-former), 25-75% plasticizer, and 0.1-15% gum (see column 1 lines 62-63, claims 1 and 15; instant claims 34 and 36). Based upon these teachings an embodiment exists (at 70% solids, with 15% gum , 15% starch and 70% plasticizer) where the gum and starch are each present at 10.5% and the plasticizer is present at 49% based on the total weight of the gel (calculated by examiner; see column 1 lines 60-7; instant claim 34). Gilleland et al. go onto teach kappa and iota carrageenan, preferably in combination, as hydrocolloid gums that gave good performance in the gel films of their invention (see column 3 lines 33-41, claims 1 and 9). In addition, Gilleland et al. also teach the particular materials to be encapsulated within the soft gel capsule that include vitamins and nutritional supplements (ingredients) in the small list of particularly envisioned items (see column 3 lines14-16, claims 15 and 18; instant claims 35 and 37). Gilleland et al. do not specifically teach the use of kappa-2 carrageenan in their invention.

Vries teaches the properties of a kappa, iota and kappa-2 carrageenan. The teachings of the reference state that molecules of kappa-2 carrageenan actually contain molecules of both kappa and iota carrageenan (see page 202 paragraph 2 lines 4-5 and table 1). In addition, Vries teaches that kappa-2 carrageenan has properties that are intermediate to both kappa and iota carrageenan, where it has improved strength over iota and improved flexibility over kappa (see table 1). In their discussion of the attributes important in the soft gel films in general, Gilleland et al. teach that flexibility and both dry and wet strength are necessary properties of a film suitable for use (see column 1 lines 23-27). Since Gilleland et al. teach that a mixture of iota and kappa carrageenan produced superior results in their invention it would have been obvious to one or ordinary skill in the art at the time the invention was made to use kappa-2 carrageenan, a mixture

at the molecular level of iota and kappa carrageenan, as the hydrocolloid gum in the Gilleland et al. invention (instant claims 34-37). Additionally, according to MPEP 2112.01, "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." This treatment results from *In re Spada*, which states that, "Products of identical chemical composition can not have mutually exclusive properties." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus based on the teachings of the prior art and absent any evidence to the contrary, the claimed viscosity characteristics of kappa-2 carrageenan would be present in the Vries modified Gilleland et al. invention and there would have been a reasonable expectation of success for the combination. Therefore claims 34-37 are obvious over Gilleland et al. in view of Vries.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36 and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 15-17, and 29-30 of copending Application No. 10/824688 (referred to as application '688 henceforth).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '688 teach a soft capsule with a second film former, plasticizer and kappa-2 carrageenan that has a viscosity of 5 to less than 10 cP at 75°C when measured at 1.5% in a solution of 0.1 molar aqueous sodium chloride (see claims 1-2 and 29; instant claim 36). Further, application '688 teaches the kappa-2 carrageenan present at 0.5% to 25% based on the total weight of the gel film, a solids content of at least 50% in the gel, and an encapsulated material that is at least one member of a short list of options that include vitamins (see claims 15 -17 and 30; instant claim 37). This combination makes obvious claims 36 and 37 of the instant application over application '688.

Claims 34 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 19-21 of copending Application No. 10/824956 (referred to as application '956 henceforth) and claims 1-2 and 19-22 of copending Application No. 10/824919 (referred to as application '919 henceforth). These two rejections are being handled together since the claims of the two copending applications have very similar language and limitations.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of application '956 teach a soft capsule with plasticizer, a second film former and low viscosity guar gum, while the claims of application '919 teach a soft capsule with plasticizer, a second film former and water soluble thermoreversible alginate (see '956 claims 1-2 and 19, '919 claims 1-2 and 19-20; instant claim 34). Further, both applications teach a solids content of at least 50%, vitamins and nutritional supplements as encapsulated materials, as well as kappa-2 carrageenan as the second film former that is present in the capsule composition (see '956 claims 2 and 20-21, '919 claims 2, 19, and 21-22; instant claims 34-35) For comparison to the instant application, the alginate and guar gum, for applications '919 and '956 respectively, would serve as the second film former that is present along with kappa-2 carrageenan. Based upon the claim language of the copending applications, the claimed components are contemplated at all concentrations. In addition, since the criticality of the claimed concentration is not stated, the routine experimentation of one of ordinary skill in the art at the time the invention was made would have found it obvious to utilize the components of the invention together and within the claimed concentrations. Therefore claims 34 and 35 are obvious over applications '919 and '956.

Claims 34-37 are provisionally rejected over claims 1-2 and 23 of copending application 10/824793 (referred to as application '793 henceforth) in view of Gilleland. Claims 34-37 are provisionally rejected over claims 1-2, 10 and 22 of copending application 10/824957 (referred to as application '957 henceforth) in view of Vries and Gilleland et al. Claims 34-35 are provisionally rejected over claims 1-2 and 10 of copending application 10/824977 (referred to as application '977 henceforth) in view of Vries and Gilleland et al.

Copending applications 10/824793, 10/824977, and 10/824957 also present issues of double patenting where in view of Vries (teaches kappa-2 carrageenan as a molecular blend of iota and kappa carrageenan that has the desirable attributes of both and minimizes their weaknesses, see page 202 paragraph 2 lines 4-5 and table 1) for applications '977 and '957 and in view of Gilleland et al. (teaches a soft capsule as a delivery system that employs a gel film, see column 2 lines 26-33) for all three of the applications, each application makes obvious the limitations of the instant claims. With the discussed modifications, each application teaches kappa-2 carrageenan with another film former and a plasticizer in a soft capsule encapsulating vitamins, where the solids content of 50% is explicitly claimed (application '793) or well within routine experimentation for one of ordinary skill in the art at the time the invention was made. In addition, based upon the claim language of the copending applications, the claimed components are contemplated at all concentrations. In addition, since the criticality of the claimed concentration is not stated, the routine experimentation of one of ordinary skill in the art at the time the invention was made would have found it obvious to utilize the components of the invention together and within the claimed concentrations. Therefore claims 34-37 are obvious over applications '793 and '757, while claims 34-35 are obvious over application'977.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caralynne Helm whose telephone number is 571-270-3506. The examiner can normally be reached on Monday through Thursday 8-4 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel or Cecilia Tsang can be reached on 571-272-0718 or 571-272-0563, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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